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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,653	08/20/2003	Toby Freyman	S63.2B-14157-US01	8819

490 7590 12/16/2010  
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EXAMINER
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WITCZAK, CATHERINE

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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12/16/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/645,653	<b>Applicant(s)</b> FREYMAN ET AL.	
	<b>Examiner</b> CATHERINE N. WITCZAK	<b>Art Unit</b> 3767	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 25-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 25, 28, 29, 30, 31, 34 and 37-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Heinrich et al (US 2005/0171563).

Heinrich et al disclose a device comprising a shaft (102); a self-expanding delivery member (114) shaped in a continuous solid cylindrical configuration (see Figures 1 and 7) made from a porous material; a therapeutic agent delivery lumen (112) in fluid communication with the delivery member (via 120); a retention member (104) configured and arranged to selectively collapse the delivery member; and a mechanism capable of applying negative pressure to the delivery lumen (see paragraph [0060], wherein Heinrich discloses a syringe being coupled to the delivery lumen - although Heinrich does not expressly disclose using the syringe to provide negative pressure, the structure of a syringe would inherently allow the syringe to be 'capable of applying negative pressure'; also see paragraph [0080] wherein Heinrich discloses the delivery lumen being in fluid communication with a source of aspiration);

As to claims 28 and 29, see paragraph [0075];

As to claims 30 and 31, see Figure 11;

As to claim 34, see Figure 3;

As to claims 37-39, wherein the shaft lumen is fully capable of acting as a 'wire lumen'.

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### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 26-35 and 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shippert et al as modified by Shippert (US 6,123,697) as modified by Tanaka (US 5,395,309).

Shippert discloses a device comprising a shaft (124); a self-expanding delivery member (100) shaped in a continuous solid cylindrical configuration (see Figure 11 – top Figure) made from a porous material; a therapeutic agent delivery lumen (lumen of 124) in fluid communication with the delivery member (via 32); and a mechanism capable of applying negative pressure to the delivery lumen (52 wherein Shippert discloses a syringe being coupled to the delivery lumen - although Shippert does not expressly disclose using the syringe to provide negative pressure, the structure of a syringe would inherently allow the syringe to be 'capable of applying negative pressure');

As to claims 26, 27, and 40, see Figure 2;

As to claims 28 and 29, see column 5, lines 7-15;

As to claims 30 and 31, see Figure 11;

As to claim 32, see Figure 15, element 132;

As to claim 33, see Figure 11, element 120;

As to claims 34 and 35, see Figure 4;

As to claims 37-39, wherein the shaft lumen is fully capable of acting as a 'wire lumen'.

Shippert discloses the claimed invention except for disclosing a retention member arranged about the delivery member. Tanaka et al disclose in Figure 1 that it is known to use an applicator comprising a sheath surrounding an expandable nasal packing member. It would have been obvious to one having

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ordinary skill in the art at the time of the invention to modify the device of Shippert with the teaching of Tanaka et al, since such a modification would simplify the insertion of the device of Shippert into the nasal cavity, by preventing the device from expanding (via the sheath member) until it has been properly positioned within the nasal cavity (see column 1, lines 5-20).

3. Claims 26, 27 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heinrich et al as modified by Shippert (US 6,123,697).

Heinrich discloses the claimed invention except for disclosing expressly the syringe capable of providing irrigation/aspiration being a Luer syringe. Shippert discloses in Figure 5 that it is known to use a Luer syringe. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Heinrich with a Luer syringe as taught by Shippert since Luer-type connections provide a secure connection between medical devices, and as such are frequently used as connectors on various medical devices. Thus, the modification of the device of Heinrich with a Luer syringe as taught by Shippert would provide the syringe of Heinrich with a syringe capable for providing a secure connection which would be compatible for use with a variety of medical devices.

4. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heinrich et al.

Heinrich et al disclose the claimed invention except for expressly disclosing the length of the delivery member. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the device of Heinrich et al with a device having a delivery member length between 5 and 40mm because Applicant has not disclosed that such a length provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would recognize that changing the dimensions of medical devices requires only routine skill in the art and is commonly employed in order to adapt device dimensions to meet the needs

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of the specific situation/patient for which the device is being used. Therefore, it would have been an obvious matter of design choice to modify Heinrich et al to obtain the invention as specified in claim 36.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE N. WITCZAK whose telephone number is (571)272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Catherine N Witzak/  
Examiner, Art Unit 3767  
/KEVIN C. SIRMONS/  
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/DONALD T HAJEC/  
Director, Technology Center 3700